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**UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS**

**IN RE: NEW ENGLAND COMPOUNDING  
PHARMACY, INC. PRODUCTS LIABILITY  
LITIGATION**

MDL No. 1:13-md-02419-FDS

**THIS DOCUMENT RELATES TO:**

*Marko v. New England Compounding Pharmacy, Inc., et al., Docket No. 13-cv-10404;*  
*Pennington v. New England Compounding Pharmacy, Inc., et al., Docket No. 13-cv-10406;*  
*Leaverton v. New England Compounding Pharmacy, Inc., et al., Docket No. 13-cv-10408;*  
*Tolotti v. New England Compounding Pharmacy, Inc., et al., Docket No. 13-cv-10413;*  
*Zavacki v. New England Compounding Pharmacy, Inc., et al., Docket No. 13-cv-10441;*  
*Letizia New England Compounding Pharmacy, Inc., et al., Docket No. 13-cv-10442;*  
*Tisa v. New England Compounding Pharmacy, Inc., et al., Docket No. 13-cv-10446; and*  
*Devilli v. New England Compounding Pharmacy, Inc., et al., Docket No. 13-cv-11167*  
*Effendian v. New England Compounding Pharmacy, Inc., et al., Docket No. 13-cv-11233*  
*Guzman v. New England Compounding Pharmacy, Inc., et al., Docket No. 12-cv-12208*

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**Motion to Dismiss Negligence, Product Liability, Battery, Civil Conspiracy, Consumer Fraud, Punitive Damages and failure to warn claims found in the Master Complaint and where adopted by any Short Form Complaint for failure to State a Cause of Action according to F.R.C.P. 12b(6).**

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### INTRODUCTION

The Defendants Premier Orthopaedic and Sports Medicine Associates of Southern New Jersey, LLC, trading as Premier Orthopaedic Associates, Premier Orthopaedic Associates Surgical Center, LLC, and Kimberley Yvette Smith, M.D., a/k/a Kimberley Yvette Smith-Martin, M.D. (Hereinafter "The Premier Defendants") respectfully move this Honorable Court to dismiss the Plaintiffs' claims as outlined below pursuant to Fed. R. Civ. P. 12(b)(6), Local Rule 7.1 and the authority cited in the attached memorandum in Support of the Motion to Dismiss.

By way of background, New England Compounding Pharmacy (hereinafter "NECP"), over a stretch of years supplied preservative free Methylprednisolone Acetate (MPA) to various hospitals, pain clinics and other medical providers. One of those providers was the Premier Defendants. On or about September 26, 2012 a recall of that medication was issued out of concern for fungal contamination of the medication in three "lots" provided to these facilities. Litigation ensued and along with the Premier Defendants, NECP and various other defendants were named as defendants. The litigation was consolidated through the Judicial Panel on Multi District

Litigation in the District Court of Massachusetts before The Honorable Dennis Saylor.

### **Premier Orthopedics**

The moving defendants operate an orthopedic practice located in Vineland New Jersey where the providers performed epidural injections using preservative free MPA obtained from New England Compounding Pharmacy. Premier had no affiliation with NECP other than to order medications, which they believed to be safe based on various representations of the company and others. Kimberly Smith-Martin has been named in the suit and has been identified as the physician who injected the medication into the patients during her procedures. Premier Orthopedics employees Dr. Smith-Martin and most of the injections were performed at Premier's Surgical Center in Vineland New Jersey - also named as a defendant. The plaintiff alleges through the Master Complaint that the moving defendants failed to take due care in choosing the appropriate entity from whom to obtain the preservative free MPA. The plaintiffs allege generally that this failure caused injury to the plaintiffs. The moving defendants deny all allegations of negligence or wrong-doing.

### **Procedural History**

Since the beginning of litigation in this case the Court has entertained several Case Management Conferences with all

interested parties in attendance. According to MDL Case Management Order No.: 7 the plaintiff steering committee (Hereinafter "PSC") was charged with preparing and filing a "Master Complaint". The Master Complaint was filed timely in November 2013. The Master Complaint identified Unifirst Corp. and Liberty Services by name only and specifically did not name any of the affiliated defendants including New England Compounding Pharmacy, Ameridose, Alaunus Pharmaceutical, Douglas Conigliaro, Gregory Conigliaro, Lisa Conigliaro, Carla Conigliaro, Glenn Chin, Barry Cadden, ARL Bio Pharma and others. It was represented to the Court that the PSC did not name these affiliated defendants because of settlement negotiations that were ongoing.

The deadline for filing motions to dismiss certain claims of the complaint was set by the Court for January 31, 2014. The Plaintiff Steering Committee has included in the Master Complaint fourteen (14) separate counts. The moving defendant now moves this Court to dismiss the counts for negligence, Consumer Fraud Violations, Battery, Failure to Warn, Agency, civil conspiracy and punitive damages.

**Motion to Dismiss**

***I. The Plaintiff's claims of negligence including plaintiffs' claims alleging failure to warn are subsumed by the New Jersey Product Liability Act.***

Plaintiff pled at Count VIII that the moving defendants failed to warn their patients that they were "being administered an unsafe, unreasonably dangerous drug compounded by NECC rather than a high quality drug produced by an FDA regulated Manufacturer." (See Master Complaint at para. 301). The plaintiffs also include a count for ordinary negligence at Count III of the complaint. The counts for lack of informed consent and negligence allege harm due to and caused by the contaminated medication, MPA.

The exclusive remedy however for when an individual is harmed by a product is the New Jersey Product liability Act, regardless of the legal theory supporting the case. As a result the plaintiff's claims for negligence are subsumed by the New Jersey Product Liability Act. The moving defendants are not subject to the New Jersey Product Liability Act because they are not considered "sellers" of the medication. Therefore the claims under Counts VIII and III must be dismissed.

***II. All claims for Battery must be dismissed.***

Under New Jersey Law the doctrine of Battery and Informed Consent are mutually exclusive of each other, requiring proof of different elements. Informed consent is a negligence concept based upon the duty of a doctor to give his/her patient appropriate information so that the patient can make an informed decision about proceeding with a particular medical course of action. Battery, on the other hand, is an intentional tort. It occurs when a doctor does not obtain the consent of his patient to perform a particular operative procedure. A required element of proving and properly pleading a claim for battery is to allege an unconsented-to touching, in this case an epidural steroid injection. Plaintiff has failed to allege that the plaintiffs did not consent to the operation/injection. As a result of this deficiency, the claims for battery must be dismissed.

***III. All claims for Civil Conspiracy Must be dismissed***

Plaintiff's claims for civil conspiracy fail to allege with any particularity an intention to agree or conspire to intentionally commit a wrongful act. Furthermore, the PSC has failed to allege that the purported civil conspiracy caused the MPA to become contaminated. The PSC alleges that a conspiracy was hatched to defraud the Massachusetts Board of Pharmacy and

circumvent their requirements. The alleged fraud was not alleged to have been directed to the plaintiffs.

Without allegations of an "agreement" to commit and unlawful act or a lawful act by unlawful means the claim is deficient. Furthermore, the PSC does not allege a causal link between the "conspiracy" and the contaminated drugs. Therefore, plaintiff's claims fall short and must be dismissed.

***IV. Plaintiffs' claims for Consumer Fraud must be dismissed in accordance with the New Jersey Consumer Fraud Act.***

The Premier Defendants are not subject to the Consumer Fraud Act (hereinafter "CFA") as plead by the plaintiffs in this case. As a matter of law and by design the legislature specifically excluded Healthcare Providers from those subject to the CFA. New Jersey Courts have also refused to hold medical professionals subject to the CFA. The Courts have explained that the CFA has consistently been interpreted not to apply to learned professionals and therefore any change must come from the legislature. Therefore, because The Premier Defendants are Healthcare providers they are not subject to the Act and all claims against the moving defendant alleging violations of the CFA must be dismissed.

***V. Plaintiffs' claims of agency must be dismissed as a matter of Law for failing to state a claim.***

At Count X of the Master complaint the plaintiff alleges that the Premier defendants were the agents of NECP when they contracted with them for the production of medication. At the very best, NECP was a vendor from whom Premier ordered medications to be administered to patients. NECP maintained this type of relationship with many if not hundreds of entities across the country and now plaintiff wishes to argue that NECP was the agent and the clinics acted as principles responsible for their actions and inactions.

As pled therefore, the plaintiff fails to make out a claim upon which relief can be granted. There are no facts or even suggestions that premier somehow controlled the process employed by NECP for manufacturing medications. Finally, the relative nature of NECP's business is not interrelated to or dependent upon Premier's operations. Therefore, plaintiff's claims for agency must be dismissed.

The plaintiff fails to pled with any specificity that the provision of medication was that of the hospitals and clinics. Without, at the very least, pleading that Premier was responsible for the manufacturing of and distribution of medications, one cannot argue that a non-delegable duty was assigned to NECP.

Furthermore, there is no evidence that the patient was under any presumption or impression that NECP was working for on or behalf of Premier Orthopedics Associates. Therefore, Premier Orthopedics cannot be held responsible for the acts or omissions of NECP based on the apparent authority theory.

***VI. Plaintiffs' claim for punitive damages must be dismissed as a matter of law.***

Claims for punitive damages are governed by New Jersey's Punitive Damages Act, *N.J.S.A. 2A:15-5.9, et seq.* [hereinafter "the PDA"]. The PDA specifies that no degree of negligence, not even gross negligence, is sufficient to establish a claim for punitive damages. Recklessness alone is insufficient; recklessness must be accompanied by deliberate action or inaction accompanied by knowledge of a high degree of probability of harm to the decedent. *N.J.S.A. 2A:15-5.12.*

Punitive damages may be awarded to the plaintiff only if the plaintiff proves, by clear and convincing evidence, that the harm suffered was the result of the defendant's acts or omissions, and such acts or omissions were actuated by actual malice or accompanied by a wanton and willful disregard of persons who foreseeably might be harmed by those acts or omissions. This burden of proof **may not be satisfied by proof of any degree of negligence including gross negligence.**

*Id.* (emphasis added).

In the present case, plaintiff has asserted that The Premier Defendants acted recklessly in administering the patient MPA from NECP. The PSC also states that the Premier Defendants acted in gross negligence when administering the MPA to its patients. While the plaintiff may have made a case of negligence they have not set forth sufficient facts to support a claim for punitive damages. Something more than gross negligence or regular negligence must be pled in order to support an award for punitive damages. There are no facts pled to support egregious, wanton and willful conduct. Therefore plaintiffs' claims for punitive damages must be dismissed.

#### **Conclusion and Prayer For Relief**

The Moving defendant, Premier Orthopedic Associates seeks an order from this Court:

1. Dismissing plaintiffs' claims for negligence, all allegations concerning violations of the New Jersey Consumer Fraud Act, Battery, Failure to Warn, Agency, Civil Conspiracy and Punitive Damages, and;
2. Dismissing the above claims as to Defendants, Premier Orthopaedic and Sports Medicine Associates of Southern New Jersey, LLC, trading as Premier Orthopaedic Associates,

Premier Orthopaedic Associates Surgical Center, LLC, and Kimberley Yvette Smith, M.D., a/k/a Kimberley Yvette Smith-Martin, M.D. as to all plaintiffs who allege such claims against the above defendant including:

- a. Marko, 1:13-cv-10404-FDS
- b. Pennington, 1:13-cv-10406-FDS
- c. Leaverton, 1:13-cv-10408-FDS
- d. Tolotti, 1:13-cv-10413-FDS
- e. Zavacki, 1:13-cv-10441-FDS
- f. Letizia, 1:13-cv-10442-FDS
- g. Tsia, 1:13-cv-10446-FDS
- h. Devilli, 1:13-cv-11167-FDS
- i. Effendian, 1:13-cv-11233-FDS
- j. Guzman, 1:12-cv-12208-FDS

And any plaintiff adopting the master complaint in the future.

Respectfully Submitted,

DATED: \_\_\_\_\_

Blumberg & Wolk, LLC

\_\_\_\_/s/Jay J. Blumberg\_\_\_\_\_

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\_\_\_\_/s/Christopher M. Wolk\_\_\_\_\_

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**Certificate of Service**

I Hereby certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filings and copies will be e-mailed or mailed via regular U.S. mail to those participants identified as unregistered this \_\_\_\_ day of \_\_\_\_\_, 2014.

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Exhibit "A"

List of Cases Relevant to The Motion to Dismiss